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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,327	08/03/2001	Robert M. Kotin	211600	7413

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/922,327	Applicant(s) KOTIN ET AL.	
	Examiner Dave T. Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-4 are pending as the result of the amendment dated January 3, 2004.

The cross-reference information as appeared on the first paragraph of the as-filed specification needs to be updated to reflect the status of the parent application.

Correction is required.

Claims 1-4 are pending for examination.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,342,390 taken with Alexander (US 5,604,090) or Carter (US 6,165,781). Although the conflicting claims are not identical, they are not patentably distinct from each other because

The patent claims are drawn to a method of genetically engineered cells *ex vivo* with the same AAV vector construct as recited in the examined claims. While the patent claims do not claim the step of introducing the genetically engineered cells containing AAV constructs in a mammal, Alexander or Carter are exemplified references that teach that AAV vectors are suitable for use to genetically engineered cells, and that the genetically engineered cells can be introduced or reintroduced into a mammal so as produce a protein of interest. As such, the examined claims and patent claims are obvious variants of one another because one of ordinary skill in the art would have been motivated to employ the genetically engineered cells as produced by the *ex vivo* transduction method set forth in the patent claims for expression of a protein of interest in a mammal, particularly since it is well recognized in the prior art that genetically engineered cells transduced with AAV vectors can be introduced or reintroduced into a mammal so as produce a protein of interest.

Thus, the examined claims and patent claims are obvious variants of one another.

Applicant's response (pages 5-6 of the response) has been considered by the examiner but is not found persuasive because of the reasons set forth in the stated rejection and for the following reasons:

Applicants mainly argues that there is no motivation to provide exogenous gene and rep protein *in trans*, however, such limitation is not relied upon for the 103 rejection when read as a whole, particularly in view of the preamble of the patent claims and the cited references. The issue is whether or not the composition as claimed in the patent

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are obvious variants of the examined claims, which is directed to a delivery method of employing *ex vivo* cells transduced with the claimed genetic constructs. The preamble of the patent claims clearly teaches every limitation as recited in the examined claim other than an additional step of employing the AAV transduced cells for delivery into a mammal. Such step wherein cell genetically engineered with a viral vector are employed to express a protein of interest *in vivo* is well-recognized in the prior art exemplified in both Alexander and Carter. As such, the examiner maintains that one of ordinary skill in the art would have been motivated to employ the AAV transduced cells as claimed in the '390 patent to deliver and express an exogenous protein carried by the AAV vectors/cells in a mammal, particularly when the concept of employing genetically engineered cells to express a protein in any environment including an *in vivo* environment is well recognized in the prior art.

Applicant further argues about the teaching away element, however, as indicated above, applicant appears to ignore the fact that every limitation and/or the concept of employing *in trans* expressing construct is already disclosed and claimed in the '390 patent. Neither Alexander nor Carter teaches in any way that their inventive concept of employing their inventive AAV particles is the only way available to be used for delivery and protein expression in a mammal. Thus, insofar as it is well-recognized that it is well established in the scientific community that exogenous protein expressing AAV carried in genetically engineered cells can be used ~~to~~ for implantation and protein expression in a mammal, one of ordinary skill in the art would have been motivated to

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employ the cells claimed in the '390 patent for delivery and protein expression in a mammal.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUORY PERIOD FOR RESPONSE EXPIRE LATER THAN **SIX MONTHS** FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER